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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/736,331

12/15/2003

Anthony R. Tremaglio JR.

09423.0028-01000

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7590

08/24/2006

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EXAMINER

KENNEDY, SHARON E

ART UNIT

PAPER NUMBER

1615

DATE MAILED: 08/24/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

Application No.

10/736,331

Applicant(s)

TREMAGLIO ET AL.

Examiner

Sharon E. Kennedy

Art Unit

1615

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☒ Responsive to communication(s) filed on 06 July 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 81-118 is/are pending in the application.
- 4a) Of the above claim(s) 84, 85, 93, 103, 104 and 112 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 81-83, 86-92, 94-102, 105-111 and 113-118 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

## Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

## Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_\_
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_

## **DETAILED ACTION**

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action or the MPEP.

### ***Election/Restrictions***

Claims 84, 85, 93, 103, 104, 112 are withdrawn from consideration as being directed to a non-elected specie.

### ***Claim Rejections - 35 USC § 102***

Claims 81-83, 86-92, 94-102, 105-111, 113-118 are rejected under 35 U.S.C. 102(b) as being anticipated by Harris et al., US 6,193,692.

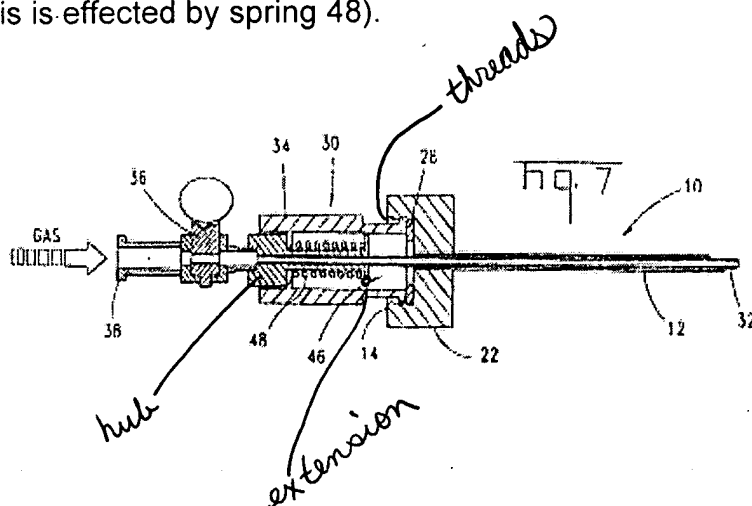
In order to more clearly explain the examiner's position, applicant's claim 81 is reproduced below with the corresponding Harris reference numerals from sheet 4 and any explanations in parenthesis.

81. An entry needle (needle assembly 10) comprising:  
a first assembly comprising a housing (stylet housing 34),  
a stylet (hollow tube 32) extending into the housing (34) and biased (note spring 48) towards a distal end of the entry needle: and  
a hub (unlabeled, see figure below "hub") adjacent the housing at a proximal end of the entry needle, the hub in connection with the stylet; and

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a second assembly comprising a cannula (sheath 12 having cutting edge 15) surrounding the stylet (32), wherein the first assembly and the second assembly seal together (o-ring 28) and are separable, and such that body fluid cannot pass through the needle when the first and second assemblies are sealed together (note embodiment of figure 10),

wherein the hub is movable from a first position to a second position, the hub in the first position indicating that the entry needle is impeded by a tissue and the hub in the second position indicating that the entry needle is substantially unimpeded by the tissue (this is effected by spring 48).



Further regarding the phrase "such that body fluid cannot pass through the needle when the first and second assemblies are sealed together" note figure 10, plug 84. See also Harris column 5, line 2 to column 6, line 8. See especially column 5, lines 6-10 and line 48. The device operates to seal by a "simple half twist or a rotation of approximately one hundred and eighty degrees of the stylet subassembly 30. Clearly, in the embodiment of figure 10, when this half twist occurs, plug 84 is rotated 180

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degrees, resulting in a prevent of any body fluid going into the needle. Note that in column 5, lines 62-64, Harris clearly states that the flow path is through the gap between the inner bore and the solid projection. Other valves are described in the following lines. In addition, valve 36 would also prevent fluid flow. The examiner takes the position that "plug" is an action word that further defines that this piece plugs the distal end of the cannula.

Regarding claims 86 and 89, the claimed "connector" is anticipated by threads on the inner lumen of sheath body 22. Regarding claim 88, see "extension" labeled in the above figure. Regarding claim 90, clearly these inner threads could be used to connect a syringe, which typically has outer threads. The limitations cited in the remaining claims are clearly shown and/or have been explained in one of the previous office actions. Regarding claim 100, this claim differs by one word, cannula as opposed to needle, and the arguments above are applicable to this claim and dependent claims as well.

### ***Response to Arguments***

The main problem with interpreting applicant's claims is that applicant terms applicant's reference numeral 312 a hub (figure 42c), when it is more accurately described as a button or knob. A hub is a device that has fluid flow. In order to find a reference that has a hub, the examiner is required to find a reference having fluid flow. The examiner did not object to this characterization in view of applicant's sheet 14,

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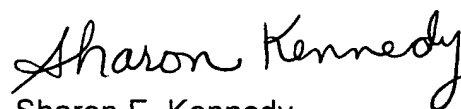
showing the alternate species of figure 23 which has a real fluid flow hub 216. Of course, Harris more closely resembles this species than any other.

***Contact Information***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sharon E. Kennedy whose telephone number is 571/272-4948. The examiner can normally be reached on Monday-Thursday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Woodward, can be reached on 571/272-8373.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Sharon E. Kennedy  
Primary Examiner  
Art Unit 1615